Response Under 37 C.F.R. §41.41
Reply Brief

Application No. 10/644,221
Paper Dated: January 14, 2008
In Reply to USPTO Correspondence of November 14, 2007
Attorney Docket No. 1217-031377

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application No.	:	10/644,221	Confirmation No.	:	6470
Applicant	:	HITOSHI NAGAOKA			
Filed	:	8/19/2003			
Title	:	INHIBITOR OF HEPATITIS B AND HIV ACTIVITY			
Group Art Unit	:	1651			
Examiner	:	Irene Marx			
Customer No.	:	28289			

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

REPLY BRIEF TO EXAMINER'S ANSWER PURSUANT TO 37 CFR §41.41(a)

Sir:

The present paper represents a Reply Brief in response to the Examiner's Answer mailed on November 14, 2007 for the above-identified Appeal, a response to which is due by January 14, 2008. The Board is respectfully requested to consider this Reply Brief directed to two points of argument raised in the Examiner's Answer.

I hereby certify that this correspondence is being submitted electronically via EFS WEB to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on January 14, 2008.

Susette McCreight

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Signature

01/14/2008
Date

1. Examiner's argument that there is a lack of necessary correlation between the *in vitro* testing and the *in vivo* effects regarding the activity of an agent in the setting of HIV-infection.

The first point of argument is that there is a lack of necessary correlation between the *in vitro* testing and the *in vivo* effects regarding the activity of an agent in the setting of HIV-infection. The Examiner cites Suzuki et al. (1989), page 372, paragraph 5 to assert that the "activity of an agent against HIV *in vitro* does not ensure that the agent will be clinically applicable in the setting of HIV-infections." Appellant respectfully traverses the Examiner's position for at least the following reasons.

Correlation refers to the relationship between *in vitro* or *in vivo* animal model assays and a disclosed or a claimed method of use. MPEP 2164.02. If there is a reasonable correlation between the disclosed *in vitro* utility and an *in vivo* activity based upon the relevant evidence as a whole, a rigorous correlation is not necessary where the disclosure of pharmacological activity is reasonable based upon the probative evidence. *Cross v. Iizuka*, 753 F.2d 1040, 1050, 224 USPQ 739, 747 (Fed. Cir. 1985). The Examiner must weigh the evidence for and against correlation and decide whether one skilled in the art would accept the model as reasonably correlating to the condition. *In re Brana*, 51 F.3d 1560, 1566, (Fed. Cir. 1995).

The Appellant establishes the necessary correlation by placing the MT-4 results in the specification. When Appellant submitted the MT-4 results in the specification, Appellant urged such results were supportive of the asserted enablement, and identified an effectiveness correlation with their enabled effective dose. The *in vitro* results in the Sawadaishi Declaration dated June 9, 1997 give further confirmation. Clinical test results corroborating and correlating anti-Hepatitis B results appear in the Sawadaishi Declaration dated February 28, 2003.

2. Examiner's argument that the working embodiment is insufficient in light of the unpredictable nature of the art and the direction's presented by Appellant.

The second point of argument is that the working embodiment cannot be the sole factor in determining enablement in light of the unpredictable nature of the art. Appellant respectfully traverses the Examiner's position for at least the following reasons.

A specification need not contain an example if the invention is otherwise disclosed in such manner that one skilled in the art will be able to practice it without an undue amount of experimentation. In re Borkowski, 422 F.2d 904, 908 (CCPA 1970). In the instant case, Appellant provides an enabling disclosure and a working example in support of said enabling disclosure. The *Lentinus edodes* infusion of the present application was previously known, as described in the specification at paragraph 7. Because the infusion was already known as a healthy drink, the amount and route of administration for the composition of the present invention was already known and appreciated in the prior art. The essence of the present invention is not primarily in the preparation and general administration of the *Lentinus edodes* infusion, therefore, but emphasizes the infusion's new and unexpected effectiveness against HIV, such that administration of the *Lentinus edodes* infusion has an indication-specific medicinal effect even when given according to prior art dosages and routes of administration. In this instance, it is precisely the artisan's knowledge of the prior art, according to *AK Stell Corp. v. Sollac and Ugine*, that makes one skilled in the art realize that the effective dose is a "healthy drink" dose, or a beverage amount dose. Appellant asks the Board to recognize that such a dose amount, a beverage dose, is a typical effective dose in herbal pharmaceutical practice both in history and throughout the world today.

It is noted that in a prior decision by the CCPA, the Appellant had claimed the method of using certain compounds to produce antidepressant activity. *In re Garner*, 427 F.2d 786, 166 USPQ 138 (CCPA 1970). In the specification, there was not a single specific example or embodiment by way of an illustration of how the invention was supposed to be practiced on any kind of host. *Id.* at 789. The specification did not disclose whether the contemplated "host" of the compound was human or an animal or what the proper dosage should be. *Id.* The Court of Customs and Patent Appeals held that the specification required an unreasonable amount of experimentation on the part of a person skilled in the art. *Id.*

The facts of the present application can be distinguished from those of Garner. The present application discloses treating a human with a healthy drink, or beverage dose, to

treat HIV, and also presents positive *in vitro* test results using *Lentinus edodes* to treat human MT-4 cells infected with HIV. In other words, in distinction to Garner, not only are the host (human), route of administration (oral), and effective dose(s) all apparent from the specification, corroborating *in vitro* evidence of the claimed medicinal indication is also provided in the specification (Table 1). Those skilled in the art thus are made aware of how to make the present mycelium infusion, how to administer it, and to whom, and what the medical benefit will be. In addition, analogous *in vivo* tests showing efficacy of the same drink in the same amount against Hep-B is also of record (Sawadaishi Declaration signed February 28, 2003).

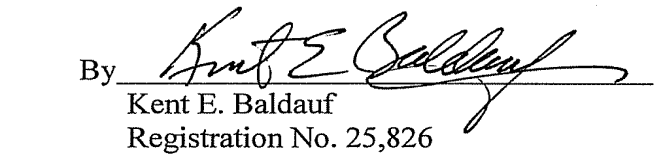
CONCLUSION

In view of the foregoing and the arguments presented in Appellant's Appeal Brief, reversal of the Examiner's rejections and allowance of claims 1-2 is therefore respectfully requested.

Any questions or comments regarding this Reply Brief should be directed to the Appellant's undersigned representative.

Respectfully submitted,

THE WEBB LAW FIRM

By 

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